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Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Reference: Docket No. 00N – 1463 (Labeling requirements for systemic antibacterial drug products intended for human use)

Dear Sirs:

The following comments are made in reference to the above document.

1. Eliminate the redundancy of the statement ("inappropriate use ... caused by susceptible microorganisms") that is proposed to appear under the product name and "Precautions" by having it appear only under the product name.
2. Add to the label a "Clinical Microbiology" section following the "Clinical Pharmacology" section under which the statement ("appropriate use ... of its susceptibility profile") that is proposed to appear under "Clinical Pharmacology" would appear. The statement, which is important, is more correctly a "Clinical Microbiology" statement rather than a "Clinical Pharmacology" statement. By creating a "Clinical Microbiology" section the label user will be able to easily recognize the statement.
3. Add to all labels dealing with antiinfectives a "Clinical Microbiology" section. The addition of a "Clinical Microbiology" section to all labels dealing with antiinfectives would more clearly identify to the user important information about the drugs use in the treatment of infections and the reasons why if not used correctly it could cause harm to the patient. Physicians and nurses are used to seeing clinical microbiology information under "Clinical Microbiology" rather than "Clinical Pharmacology". They refer to the "Clinical Pharmacology" to obtain information about the behavior of the drug in the patient (ex. absorption, excretion).

Sincerely,

Harold V. Silver

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